



**LITERATURE DATABASE
FOR EVALUATING HIV/AIDS
INTERVENTIONS**

Version 1.0

Lori Bollinger
Katharine Cooper-Arnold
John Stover

The FUTURES Group International

March 2002

I. Literature Review

A. Introduction

HIV/AIDS interventions are currently being designed and carried out in the developing world. Some of these interventions are evaluated by randomized controlled trials, with accompanying cost analyses, and others are evaluated with small cross-sectional surveys. The process of designing and evaluating interventions can be difficult and time-consuming due to the wide variety and complexity of epidemiologic and ethical issues related to HIV/AIDS. In order to provide assistance to those responsible for implementing prevention studies and to those studying the results, a systematic review of the HIV/AIDS and sexually transmitted infections (STI) intervention literature was conducted. The literature review was used to develop a searchable Excel workbook of published and non-published HIV/AIDS intervention studies in the developing world.

B. Search Strategy Methods

Between January and June 2001, studies were identified by searching electronic databases of the peer-reviewed medical journals and the "gray" literature (literature not formally published such as research reports, policy documents, dissertations, and conference abstracts). Studies published between 1981 and June 2001 were reviewed for developing countries. The search utilized both formal and *ad hoc* methods, and consisted of two stages. In the first stage, a systematic electronic and manual search was conducted of peer-reviewed and non-reviewed articles to identify reports of prevention interventions targeting risk reduction of HIV and STIs in developing world populations. Medical databases included:

- Medline
- AIDSline
- Popline

as well as a selective review of

- EMBASE
- BIOSIS
- SCISEARCH
- SIGLE

Additionally, several websites were accessed including:

- XIII International AIDS Conference, 2000 in Durban, South Africa
- UNAIDS
- id21 (from UK Department for International Development)
- Family Health International (FHI) including AIDSCAP
- The Futures Group International (TFGI)

- Abstracts from global AIDS conferences such as The Third USAID HIV/AIDS Prevention Conference.

Manual search techniques, including systematic visual searching of the bibliographies of articles identified during the online searches in health, medical, and social science journals, and books, were also conducted as well as a review of final project reports and country program evaluations from various consulting firms.

The second stage identified the interventions that met the criteria, defined additional MeSH and freetext terms from these first-round abstracts, and performed a second online and manual search incorporating these new terms. This information was used to devise a search strategy designed to be more sensitive than the first. (Dickersin et al., 1994) Additionally, the reference lists for all articles identified in the first search were reviewed. The second search thus provided information on the indexing and authors of the interventions that were not picked up by the first search. The sampling period was ended when searches produced similar results and when previous search results became outdated (Kim et al., 1999).

When pre-and post-intervention data were not reported for an intervention, addresses or email addresses were obtained and requests for more complete information on data and costs were sent to the first authors of the reports. If the author returned additional data, the article was included in the sources. No attempt was made to verify data in the published articles. Since emails were written to authors of studies when additional data or clarifications were needed, some information relating to studies in this systematic review may not have been published previously or may differ slightly from that in the published article.

C. Inclusion/Exclusion Criteria

Inclusion and exclusion criteria identified well-designed studies from which conclusions about the effectiveness of interventions can be drawn.

Inclusion:

Studies were included if they:

1. defined an HIV/AIDS or STI prevention intervention in a developing world country
2. provided pre-and post-program measures
3. provided at least one behavioral (e.g., condom use, number of sex partners, age at first sexual activity, sexual contact with CSWs, changes in risky sexual or STI treatment- seeking behavior), biological (e.g., STI/HIV incidence or prevalence rates, minimum inhibitory concentration, or economic (costs, benefit-cost, cost-effectiveness, or cost-utility) endpoint.

Exclusion:

Studies were excluded if they were:

1. conducted before 1981
2. reported as conference abstracts without data
3. reported without pre- and/or post-intervention data
4. reported as attitudes and knowledge surveys only, or interventions with ethnographic data only.

However, there were some exceptions to these inclusion/exclusion criteria. For example, an STI treatment intervention conducted in the pre-HIV era (1967) was added because it was a well-designed study with clear biologic endpoints that are still relevant to the relationship of STI treatment on behavior change. In addition, not all relevant studies are included in this review. Although non-English speaking studies were not purposely excluded, only one non-English (Spanish) intervention was used. It may be that studies published in languages other than English will result in significant articles being omitted from the literature review. (Dickersin et al., 1994).

D. Search Results

Data were entered into an Excel workbook and data entry was validated by taking a random sample of 20% of the articles and rechecking that the data had been entered correctly. All study references, information, and results were entered into the "Sources" and "Summaries" worksheets, respectively (see below for further documentation). Behavioral evaluation data focused mainly on knowledge of infection, degree of multiple and type of partners (CSWs, casual, girlfriend, and/or wife), condom accessibility and use, type of sexual encounters, and intravenous drug user (IDU) behavior changes. STI treatment studies focused on biologic and epidemiologic endpoints of STI incidence and prevalence, percent of population cured, condom use and accessibility, and treatment-seeking behavior. In many cases behavioral data points were established for groups about which there have been little or no data available before the program's interventions. Most of the behavioral evaluations data collection involved combinations of surveys with individual or focus group interviews or combining quantitative with qualitative data; thus, statistics indicator data were often complemented by detailed contextual data describing perceptions of peer social norms and sexual behavior. The studies used several different qualitative and quantitative methods such as semi-structured interview, free-listing, explanatory models, microbiological testing, and sentinel surveillance.

Two hundred and forty-two studies representing six categories of research design and cost analyses were retrieved. Of these 242 studies, 201 studies were abstracted into the "Summaries" worksheet and included the following types of design:

Table 1. Studies by Design

Study Design	Number of Studies
Randomized trials (controlled/non-controlled)	21
Quasi-experimental	11
Prospective cohort/longitudinal (with/without controls)	67
Cross-sectional	56
Other*	41
Unclear	5

*Includes pre/post surveys, cluster, crossover, retrospective record review, case studies, and costing analyses.

Of the 41 articles that were not abstracted into "Summaries", missing data have been requested; the articles were, nevertheless, listed in "Sources".

E. Study Limitations

As with any literature search, "the quality of the data is limited by the quality of the studies" reviewed (Kunz, Oxman, 1998). Rigorous evaluation research design was not feasible or appropriate for every intervention. Such designs were used only in the case of a demonstration project, to test a new intervention, or to answer a specific research question. Valid assessment of the effectiveness of behavior change interventions presents numerous methodological and practical problems, including:

- no or inadequate control group
- limited follow-up (< 6 months)
- intervention fatigue in which after a long intervention period, behavior change either remained the same or reversed
- high attrition (with subsequent loss of statistical power when comparing two groups)
- self-reported data
- nonrandom allocation of study subjects
- lack of internal validity including confounding, information, and selection bias
- publication bias.

Note that any nonrandom procedures by which the study subjects were chosen may have resulted in selection bias, especially if participants with certain characteristics for HIV/STIs leave the study in disproportionate numbers. In

historical cohort or case-control studies, when data are obtained by personal interview, information bias may occur. Verifying accuracy of behavior may be difficult if clinic records or condom distribution forms are not completely reliable and cannot be used to support evaluation data. (Taha et al., 1996; Walden et al., 1999). However, studies done on the reliability and validity of self-reported sexual behavior found that information obtained from self-administered questionnaires and face-to-face interviews was largely consistent from couples attending STI clinics. (Walden et al., 1999; James et al., 1991; Upchurch, 1991).

Studies may also experience confounding bias. For example, uncontrolled cohort studies do not account for trends in behavior and controlled cohort studies may be confounded by the voluntary nature of VCT (Muller, et al., 1995). Results may also be confounded by the characteristics of the selected intervention and control groups.

Additional methodological problems are inherent in non-random studies evaluating associations of interventions to behavior and clinical endpoints. Problems may include differential intensity of interventions; differences in underlying risk for the study population, and choice of effect measure (artefactual bias)(Egger et al., 1997). For example, STI incidence rates may be inaccurate if they do not count asymptomatic STIs. If asymptomatic rates are higher in one study group, intervention effects may be unreliable. In spite of these data and methodologic irregularities, small, non-random, noncontrolled, or observational studies may provide valuable information that is complementary to randomized controlled trials.

Therefore, complete identification of all studies is particularly important to avoid publication bias. Note that access to “gray” literature remains difficult due to incomplete data or nonpeer review. The advent of specific gray literature databases such as SIGLE, produced by the European Association for Grey Literature, has improved the situation, but much research remains inaccessible. This literature is not trivial, and interventions reported there may not see full publication elsewhere.

II. Structure of the Database

A. Description of Fields

The database is in an Excel workbook, containing three worksheets entitled “Summaries”, “Sources by Topic”, and “Sources by Author ID”:

1. The “Summaries” worksheet includes 13 fields:

- Category - intervention category.
- Subcategory - subcategory within each intervention category.
- Source ID (Author) - a unique identification assigned to each study using the first letter of the first author's last name and an identifying number.

- Author - first author.
- Year of Intervention - approximate year(s) the intervention took place.
- Country - country of intervention.
- Primary intervention - intervention activities.
- Study design - epidemiologic study design or type of cost analysis (including whether a control or comparison group was included).
- Sample size - number of study participants.
- Population - description of study participants.
- Location - study sites.
- Months of Intervention - length of intervention in months.
- Results - study results.

2. The "Sources by Topic" worksheet includes eight fields, sorted first by the "Category" field and then by the "Subcategory" field:

- Category - intervention category.
- Subcategory - subcategory within each intervention category.
- Country - country of intervention.
- Source ID (Author) - a unique identification assigned to each study using the first letter of the first author's last name and an identifying number.
- Author - authors of article or report.
- Year - year of publication.
- Title - title of article or report.
- Publication information - full citation.

3. The "Sources by Author ID" worksheet is identical to the "Sources by Topic" worksheet, except that it is sorted by the "Author ID" field.

Not all fields in the "Summaries" worksheet could be completed for all studies. In some cases, the year the intervention was performed, the study design, or the exact pre and post-survey sample population numbers (especially in conference abstracts) were unclear or left out.

B. Intervention Categories

The studies were divided into the following intervention categories, with some categories also containing sub-categories:

- Behavior Change
 - Community mobilization
 - Condom distribution/promotion
 - Condom social marketing
 - IDUs
 - IE&C
 - MSM
 - Peer education
 - PLWHA

- School-based
 - VCT
 - Workplace programs
- Blood Safety
- Prevention of Maternal-to-Child Transmission (PMTCT)
- Other Mitigation
- Orphan Care (OVC)
- Sexually transmitted Diseases (STIs)
 - Divided into primarily HIV and non-HIV-related interventions
- Treatment and Support
 - Home-based care
 - Clinic-based care
 - Hospital-based care

The economic data in the interventions either came from resource use information, using some assumed unit cost values, or from data on charges for health care, such as counseling, laboratory, drug treatment, or hospital- or home-based costs. The number of resource items included in the calculation of total costs varied considerably from study to study. Patient specific information was available for only a limited number of resources and fixed cost estimates were assumed for others. Some studies conducted sensitivity analyses that investigated robustness to various assumptions including unit costs, assumed resource use values, and discount rates.

III. Database Tutorial

A spreadsheet version of the literature review has been created for use with Microsoft Excel. The Excel workbook permits the user to search for study data by various fields. This Excel workbook may be downloaded and allows a great deal of flexibility in customizing a literature search on HIV/AIDS interventions. In addition, more recent studies may be added to the user's version of the spreadsheet. This tutorial covers the key steps in installing and using the Intervention spreadsheet. It assumes that you have an IBM-compatible computer running Windows 3.1 or Windows 95 or higher and that you are familiar with the basic operation of Windows programs and terminology.

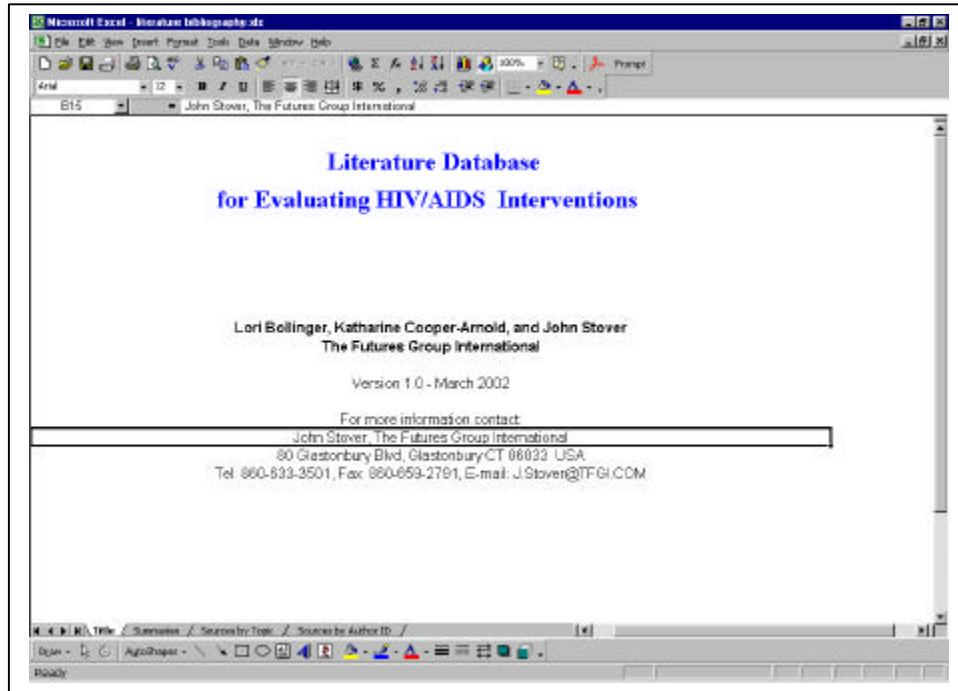
A. Downloading the HIV/AIDS Literature Database in Excel

1. Type in the web site address at www.tfgi.com.
2. Click either on "Publications" (at the left-hand side of the page), or on "Resources" and then "HIV/AIDS".
3. Click on "HIV/AIDS Literature Database" to download. You may save the file to a floppy disk or to your hard drive.

B. Opening the Literature Database Excel Spreadsheet

1. To open the Excel workbook, first start the Microsoft Excel program.

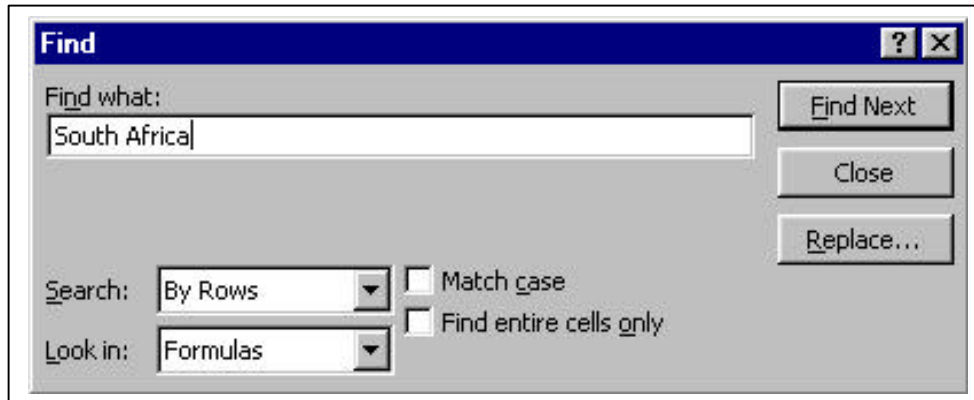
2. To load the database, first select "File" and "Open" from Excel. Then select the file titled "Literature Database.xls". The file will automatically load, and you will be placed in the title page shown below:



3. At this point the database workbook has been loaded. At the bottom of the screen are tabs allowing you to navigate through the spreadsheet (e.g., Title, Summaries, Sources by Topic, Sources by Author ID). You can move through the spreadsheet by clicking on the appropriate tab.

C. Examining and Editing the Worksheets

1. To search for a particular study by either country, intervention category, year, author or any other field, you can hit Control F and type in the name of the variable that you would like to find.



- If you were searching for South Africa in the Summaries worksheet, the results would appear as below. If you would like to continue searching for all studies that took place in South Africa, hit "Find Next" until you have found all of the South African studies.

Microsoft Excel - Goals						
File Edit View Insert Format Tools Data Window Help						
A B C D E F G						
1	Category	Sub-category	Source ID (Author)	Author	Country	Year of Intervention
2	BEHAVIOR CHANGE	Community mobilization	M16	Madhavan	Zimbabwe	1991-1997
3	BEHAVIOR CHANGE	Condom distribution/promotion	M27	Marcella	South Africa	2000?
4	BEHAVIOR CHANGE	Condom distribution/promotion	T6	Forcette	Mexico, DR, Antigua	
5	BEHAVIOR CHANGE	Condom distribution/promotion	R6	Rosemary Hegeler	Tanzania	1989-1994
6	BEHAVIOR CHANGE	Condom distribution	A4	Antonia M. Stoll	Brazil	1994
7	BEHAVIOR CHANGE	Condom distribution	R2	Roe	India	1995

From 1991-1997, the M16 study project involves distribution and costs (including donated condoms and opportunity costs) averaged US\$1.75/condom including \$0.04/piece needed, and \$0.02/condom distributed.

Program would distribute 6,000 condoms in a cost of \$4,200 (\$0.70/condom distributed); 5.9 HIV, 98 syphilis, and 23 gonorrhea cases averted. Public sector health policy costs \$13,090 on oral HIV/AIDS, \$1,074 averted syphilis, and 60 averted treatment costs - net savings of \$9,163. Program generated savings of \$5,421 if HIV prevalence in CSWs is 25% rather than 50.3% and savings of \$3,591 if each CSW on average 10 rather than 25 partners/year. A program focusing on non-CSWs with only one partner a year could save \$129.

US\$17,000-171,000 (small peer education program (US\$500/condom averaged cost); 50,000-180,000 condoms/syphilis distributed reaching 170-1,800 CSWs. Discounted opportunity and secondary HIV infection avoided \$400-\$1,000. Using conservative estimates of lifetime direct treatment costs (ignoring productivity losses), the benefit to cost ratio was 3.5 to 1 (assuming 2 secondary infections/primary infection averted) to 7.4 to 1 (assuming 6 secondary infections averted). If the indirect benefits (productivity losses from early death) were included, this benefit to cost ratio would have significantly increased.

US\$0.06/condom; In 1992, the year when the most condoms were bought, US\$0.2 million was enough to protect virtually all the commercial sex sector in this country.

US\$0.07/condom; For riskier high school students.

For CSWs using condoms reduced the price of condoms by 43.7%.

- You can sort any of the worksheets by a particular field or fields. To sort the entire worksheet, click on the upper left portion, which highlights all of the data. Note that if you only highlight one column, the rest of the columns

will not be sorted and the records will no longer match for all fields. After highlighting the data, go to "Data" then to "Sort". This command allows you to sort by one primary column and then by two other columns as shown below:



For example, if you would like to sort by Behavior Change as the category and Condom distribution/promotion as the subcategory, the results of this sort are shown in the screen below:

Category	Subcategory	Source ID (Number)	Author	Year of Publication	Country	Primary Intervention	Study Design	Sample Size
1. BEHAVIOR CHANGE	Condom distribution/promotion	10	The Date of d.	1991-1998	Franklin	peer education, condom distribution, 37 countries	randomized, pre/post quantitative survey	2,000
2. BEHAVIOR CHANGE	Condom distribution/promotion	11	Wong et al.	1991-1998	Malaysia	community-based HIV education, condom promotion	PRE-POST	4,000
3. BEHAVIOR CHANGE	Condom distribution/promotion	12	de la Haye et al.	1991-1998	Malawi	peer education, condom distribution	pre-post quantitative survey	2,000
4. BEHAVIOR CHANGE	Condom distribution/promotion	13	Wong et al.	1991-1998	Malawi	peer education, condom distribution	pre-post quantitative survey	2,000
5. BEHAVIOR CHANGE	Condom distribution/promotion	14	Wong et al.	1991-1998	Malawi	peer education, condom distribution	pre-post quantitative survey	2,000

4. All study information and results are located in the "Summaries" worksheet and citation information is located in the two "Sources" worksheets. If you want to get the complete citation for any study in the "Summaries" worksheet, you can find the study in either of the "Sources" worksheets by referencing the Source ID for that study. For example, if you want the

complete citation for study P1, as seen in the Source ID (Author) column of the "Summaries" worksheet,

Microsoft Excel - Goals

File Edit View Insert Format Tools Data Window Help

Goal

	A	B	C	D	E	F	G	H	I
1	Category	Subcategory	Source ID (Author)	Author	Year of Information	Country	Primary Information	Study Design	Sample Size
2	REVIEWER CHANGE	Peer education	MS	Tan Dine et al.	1993-1999	South Africa	peer education, random distribution, CT services	cross-sectional analysis, quantitative survey	2,800s
3	REVIEWER CHANGE	Community mobilization	MS	Pearl et al.	1991-1992	Malawi	community-based HIV education, random population	RCT	2,400
4	REVIEWER CHANGE	Community mobilization	MS	Martinez et al.	1991-1997	Peru	peer education to reduce TB/HIV	cohort	1,000 FTV study

Ready

you will find it by going to one of the "Sources" worksheets, hitting "Control F," typing in "P1," and finding P1 in the Source ID (Author) column as seen below:

[illegible]

5. If you enter new or change old data in the user version of the spreadsheet, you should "Save" the file before exiting. This step will enable you to save the changes that were made.

Additionally, any data from the user spreadsheet can be extracted to a PowerPoint file for presentation purposes.

Acronyms and Abbreviations

AIDS	acquired immunodeficiency disease
CSW	commercial sex worker
FSW	female sex worker
HIV	human immunodeficiency virus
ID	identification
IDU	injection drug user
IE&C	information, education, and communication
MeSH	medical subject headings in medical literature databases
MIC	minimum inhibitory concentration (of a drug)
MSM	men who have sex with men
NEP	needle exchange programs
NS	not statistically significant
OI	opportunistic infection
OVC	orphans and vulnerable children
PC-C	prospective cohort with a comparison group
PC-NC	prospective cohort without a comparison group
PLWHA	people living with HIV/AIDS
PY	person years
RCS-C	repeat cross-sectional with a control group
RCS-NC	repeat cross-sectional without a control group
RCT	randomized controlled trial
STI	sexually transmitted infection
VCT	voluntary HIV counseling and testing

References

1. Dickersin K, Scherer R, Lefebvre C. Systematic reviews: identifying relevant studies for systematic reviews. *BMJ* 1994;309:1286-91.
2. Kim P, Eng TR, Deering M, Maxfield A. Published criteria for evaluating health related web sites: review. *BMJ* 1999;318(7184):647-9.
3. Kunz R, Oxman AD. The unpredictability paradox: review of empirical comparisons of randomised and non-randomised clinical trials. *BMJ* 1998;317:1185-90.
4. Taha ETT, Canner JK, Chipangwi JD, Dallabetta G, Yange L-P, Mtimavalye LAR, Miotti PG. Reported condom use is not associated with incidence of sexually transmitted diseases in Malawi. *AIDS* 1996;10:207-12.
5. Walden VM, Mwangulube K, Makhumula-Nkhoma P. Measuring the impact of a behavior change intervention for commercial sex workers and their potential clients in Malawi. *Health Edu Res* 1999;14(4):545-54.
6. James NJ, Bignall CJ, Gillies PA. The reliability of self-reported sexual behavior. *AIDS* 1991;5:333-6.
7. Upchurch DM. Interpartner reliability of reporting of recent sexual behaviours. *Am J Epidemiol* 1991;134:1159-65.
8. Muller O, Sarangbin S, Ruxrungtham K, Sittitai W, Phanuphak P. Sexual risk behaviour reduction associated with voluntary HIV counselling and testing in HIV-infected patients in Thailand. *AIDS Care* 1995;7(5):567-72.
9. Egger, M, Smith GD, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997;315:629-34.